

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE / 586191**

Applicant: Hiromitsu FUSE et al.

Title: DRUG FOR PREVENTING AND TREATING  
ATHEROSCLEROSIS (as amended)

Appl. No.: Unassigned

International 1/14/2005

Filing Date:

371(c) Date:

Examiner: Unassigned

Art Unit: Unassigned

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

**TIMING OF THE DISCLOSURE** ~~20 Rec'd PTO 14 JUL 2006~~

The listed documents are being submitted in compliance with 37 CFR §1.97(b), within three (3) months of the date of entry of the national stage as set forth in 37 CFR §1.491.

**RELEVANCE OF EACH DOCUMENT**

A copy of the International Search Report is attached setting forth the portion of each document cited therein which was considered relevant by the examiner. An English-language counterpart of the foreign-language documents has been provided where readily available. English language abstracts are provided for each foreign-language document. The absence of a full translation or an English-language counterpart document does not relieve the PTO from its duty to consider any submitted document (37 CFR §1.98 and MPEP§609).

Applicants respectfully request that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

Although Applicant believes that no fee is required for this Request, the Commissioner is hereby authorized to charge any additional fees which may be required for this Request to Deposit Account No. 19-0741.

Respectfully submitted,

*Michael Maebius*

*Reg. No. 34,717*

By \_\_\_\_\_

  
Stephen B. Maebius  
Attorney for Applicant  
Registration No. 35,264

Date July 14, 2006

FOLEY & LARDNER LLP  
Customer Number: 22428  
Telephone: (202) 672-5569  
Facsimile: (202) 672-5399

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO		<i>Complete if Known</i>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		<b>Application Number</b>	Unassigned <i>107586191</i>
Date Submitted: July 14, 2006		<b>Filing Date</b>	1/14/2005
(use as many sheets as necessary)		<b>First Named Inventor</b>	Hiromitsu FUSE
Sheet	1	<b>Group Art Unit</b>	Unassigned
		<b>Examiner Name</b>	Unassigned
		<b>Attorney Docket Number</b>	023312-0127

## **U.S. PATENT DOCUMENTS**

## **FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document		Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>	
		Office <sup>3</sup>	Number <sup>4</sup> Kind Code <sup>5</sup> (if known)					
	A2	JP	2000-333682	A	Seikagaku Kogyo Co. Ltd.	12/05/2000		A
	A3	JP	11-18778	A	Seikagaku Kogyo Co. Ltd.	01/26/1999		A
	A4	WO	03/078624	A1	Takeda Chemical Ind. Ltd.	09/25/2003		A

#### **NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	A5	BOBRYSHCHEV et al., "Phenotype determination of anti-GM3 positive cells in atherosclerosis lesions of the human aorta, Hypothetical role of ganglioside GM3 in foam cell formation," <i>Biochimica et Biophysica Acta</i> , 2001, vol. 1535, pp. 87-99.	
	A6	FUKUMOTO et al., "Expression Cloning of Mouse cDNA of CMP-NeuAc:Lactosylceramide $\alpha$ 2,3-Sialyltransferase, an Enzyme That Initiates the Synthesis of Gangiosides," <i>J. Biol. Chem.</i> , April 2, 1999, vol. 274, no. 14, pp. 9271-9276.	
	A7	HARA et al., "Characterization and Changes of Glycosphingolipids in the Aorta of the Watanabe Heritable Hyperlipidemic Rabbit," <i>J. Biochem.</i> , 1991, vol. 109, pp. 904-908.	
	A8	MELKERSON-WATSON et al., "Purification to Apparent Homogeneity by Immunoaffinity Chromatography and Partial Characterization of the GM3 Ganglioside-forming Enzyme, CMP-Sialic Acid:Lactosylceramide $\alpha$ 2,3-Sialyltransferase (SAT-1), from Rat Liver Golgi," <i>J. Biol. Chem.</i> , March 5, 1991, vol. 266, no. 7, pp. 4448-4457.	
	A9	PROKAZOVA et al., "Ganglioside GM3 stimulates the uptake and processing of low density lipoproteins by macrophages," <i>Biochemical and Biophysical Research Communications</i> , May 31, 1991, vol. 177, no. 1, pp. 582-587.	
	A10	USUKI et al., "Toward the Understanding of Glycopilid GM3 Functions – Application of Metabolic Inhibitors," <i>Nippon Yuka Gakkaishi</i> , 1997, vol. 46, no. 10, pp. 1075-1086 (with English abstract).	

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

**\*EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO)

<sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.  
<sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Alexandria  
WASH 1650547 1